



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/811,661

03/29/2004

Christian Woll

55925/2

2443

71130 7590 12/08/2008
SEYFARTH SHAW LLP
WORLD TRADE CENTER EAST
TWO SEAPORT LANE, SUITE 300
BOSTON, MA 02210-2028

EXAMINER

ARAJ, MICHAEL J

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

12/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/811,661	Applicant(s) WOLL ET AL.	
	Examiner MICHAEL J. ARAJ	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-32 is/are pending in the application.
- 4a) Of the above claim(s) 24-32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 7-12 and 16-22 is/are rejected.
- 7) ☒ Claim(s) 4-6 and 13-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 1-15 have lines, numbers and letter that are not uniformly thick and well defined, clean and durable. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 8, 10-12, 16-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Laub (US 4,808,163). Laub teaches a device capable of positioning bone segments comprising: a flexible guide wire 26 having a proximal end and a distal end; a distal stop 22 disposed on said guide wire 26 about adjacent to said guide wire distal end; a proximal stop 31 disposed on said guide wire 26 about adjacent to said guide wire proximal end; and a flexible tube 11 disposable over said guide wire 26 and having a sidewall including a radially expandable anchor portion 16 adapted for

radial expansion upon compression of said tube 11 between said distal stop 22 and said proximal stop 31; wherein said anchor portion 16 is disposed toward said distal end and comprises a plurality of evenly spaced ribs 18 formed between a plurality of longitudinal slots 17 disposed through said sidewall; wherein said radially expandable anchor 16 portion is adapted to collapse upon relaxation of compression forces between distal and proximal segments of said tube and adapted to collapse upon application of tension between distal and proximal segments of said tube 11; further comprising at least one semi-annular cut 14 in said tube 11.

Concerning the claim language of “a dilator having a tapered distal surface, an at least partially transverse proximal surface and a tubular inner surface defining a longitudinal through hole; said dilator being disposable on said guide wire wherein said guide wire extends through said through hole and wherein said at least partially transverse proximal surface serves as said distal stop,” it is noted that Laub discloses the use of a hollow needle to introduce guidewire 26 into vein 36. It is the examiner's position that this needle would inherently include all of the structural features of the dilator. Because any needle has a transverse dimension at its proximal end which would appear as an annulus when viewed from the proximal end, it is believed the needle mentioned by Laub would thereby have “an at least partially transverse proximal surface.” Further, it is believed that the longitudinal through hole provides for the “countersunk” recitation of claim 3.

Claim Rejections - 35 USC § 103

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laub (US 4,808,163) as applied to claim 1 above and further in view of Culbert et al. (U.S. 6,648,890). Laub teaches all of the limitations of the present invention except the device comprising a bioactive material.

Culbert et al. teaches a related device for fixing together two bone segments which, as mentioned in lines 33-43 of column 10, “may contain one or more bioactive substances, such as antibiotics, chemotherapeutic substances, angiogenic growth factors, substances for accelerating the healing of the wound, growth hormones, antithrombogenic agents, bone growth accelerators or agents, and the like. Such bioactive implants may be desirable because they contribute to the healing of the injury in addition to providing mechanical support. “

It would have been obvious to one having ordinary skill in the art at the time of the present invention to incorporate bioactive substances as taught by Culbert et al. into one or more parts or portions of the device taught by Laub so as to improve the healing of injury.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laub (US 4,808,163) as applied to claim 11 above and further in view of Culbert et al. (U.S. 6,648,890). Laub teaches all of the limitations of the present invention except the ribs of said anchor portion include a textured surface.

Culbert et al. teaches a related device for fixing together two bone segments in which, as mentioned in lines 46-48 of column 10, "osteoincorporation may be enhanced by providing a micropitted or otherwise textured surface on the anchor components."

It would have been obvious to one having ordinary skill in the art at the time of the present invention to form a textured surface as taught by Culbert et al. on the ribs of the device of Laub to enhance osteoincorporation.

Allowable Subject Matter

Claims 4-6 and 13-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 23 is allowed.

Response to Arguments

Applicant's arguments filed on September 17, 2007 have been fully considered but they are not persuasive. In response to Applicant's argument that Laub is nonanalogous art, it has been held that the determination that a reference is from a nonanalogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. In *re Wood*, 202 USPQ 171, 174. In this case, the device might be used for a different

purpose but it still has the same structure limitation as claimed. Whether the needle is removed or not does not change on how Laub reads on the presently rejected claims.

Also, in response to Applicant's argument that the stylet of Laub performs a function that is completely different than the dilator of the Applicant's invention, the fact that Applicant uses the apparatus for a different purpose does not alter the conclusion that its use in a prior art device would be prima facie obvious from the purpose disclosed in the reference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ARAJ whose telephone number is (571)272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Araj/
Examiner, Art Unit 3775
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733